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| PTO/SB/08A and B (08-03) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for Form 1449A/PTO | APPLICATION NO.: 10/674,268 | FILING DATE: September 29, 2003 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | FIRST NAMED INVENTOR: Michael Fantuzzi | ART UNIT: 1652 |
| | EXAMINER NAME: Kosson, Rosanne | ATTY. DOCKET NO.: 33503/US |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-------------|-----------------------------------|---------------|---------------------------------------|---|
| EXAMINER INITIALS* | Cite No. | PATENT NUMBER | ISSUE DATE | Name of Patentee of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code* (if known) | MM-DD-YYYY | | |
| | A1. | 4,029,760 | 06/1977 | De Roeck born Holtzhauer | |
| | A2. | 4,559,222 | 12/1985 | Enscore et al. | |
| | A3. | 5,290,605 | 03/1994 | Shapira | |
| | A4. | 5,298,246 | 03/1994 | Yano et al. | |
| | A5. | 5,431,916 | 07/1995 | White | |
| | A6. | 5,716,928 | 02/1998 | Benet et al. | |
| | A7. | 5,858,401 | 01/1999 | Bhalani et al. | |
| | A8. | 5,968,987 | 10/1999 | Charman et al. | |
| | A9. | 5,980,939 | 11/1999 | Kim et al. | |
| | A10. | 6,096,338 | 08/2000 | Lacy et al. | |
| | A11. | 6,121,234 | 09/2000 | Benet et al. | |
| | A12. | 6,174,547 | 01/2001 | Dong et al. | |
| | A13. | 6,197,349 | 03/2001 | Westesen et al. | |
| | A14. | 6,200,550 | 03/2001 | Masterson et al. | |
| | A15. | 6,207,137 | 03/2001 | Shuch et al. | |
| | A16. | 6,284,268 | 09/2001 | Mishra et al. | |
| | A17. | 6,368,618 | 04/2002 | Jun et al. | |
| | A18. | 6,503,483 | 01/2003 | Shuch et al. | |
| | A19. | 6,552,004 | 04/2003 | Elazhary et al. | |
| | A20. | 6,569,463 | 05/2003 | Patel et al. | |
| | A21. | 6,630,170 | 10/2003 | Balkus et al. | |
| | A22. | 6,730,319 | 05/2004 | Maeder et al. | |
| | A23. | 6,790,465 | 09/2004 | Weissman | |
| | A24. | 7,588,786 | 09/2009 | Khan et al. | |
| | A25. | 7,713,523 | 05/2010 | Fantuzzi et al. | |

| U.S. PUBLICATION DOCUMENTS | | | | | |
|----------------------------|--------------------------|-----------------------------------|---------------------|--|---|
| EXAMINER INITIALS* | Cite No. ¹ | PUBLICATION NUMBER | PUBLICATION DATE | Name of Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code* (if known) | MM-DD-YYYY | | |
| | B1. | 2003/0108600 | 06/2003 | Okibayashi et al. | |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RK/

| | | |
|--|---|------------------------------------|
| PTO/SB/08A and B (08-03) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for Form 1449A/PTO | APPLICATION NO.: 10/674,268 | FILING DATE: September 29, 2003 |
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(Use as many sheets as necessary)

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS ¹ | Cite No. ¹ | DOCUMENT NUMBER | PUBLICATION DATE | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|-----------------------------------|--------------------------|---|---------------------|--|---|----------------|
| | | Country Code ² - Number ³ - Kind Code ⁴ (if known) | MM-DD-YYYY | | | |
| | C1. | JP S57142911 | 09/1982 | Motoyama et al. | | √ |
| | C2. | JP 5770815 | 05/1982 | Furointo Sangyo KK | Abstract only. | √ |
| | C3. | JP S57042616 | 03/1982 | Freund Sangyo KK | | √ |
| | C4. | WO 98/056368 | 12/1998 | Board of Regents, The University of Texas System | | |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIALS ¹ | Cite No. ¹ | Include name of Author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
|-----------------------------------|--------------------------|---|----------------|
| | D1. | Office Action dated December 7, 2010, JP 2006-528309, 5 pages (including English translation) | |
| | D2. | Office Action dated July 4, 2011, Israel Patent Application No. 174624, 2 pages | |
| | D3. | Anderson Provisional Patent Application No. 60/253,874, David M. Anderson, Applicant, filed November 29, 2000, 21 pages | |
| | D4. | Al-Hasso, Shahla, "Coenzyme Q10: A Review," <i>Hospital Pharmacy</i> , Vol. 36, No. 1, pp. 51-55, 2000 Facts and Comparisons | |
| | D5. | AUTHOR UNKNOWN, Oilseeds International Ltd., Rice bran oil- a health benefit, http://www.oilseedssf.com/products/prod.rice.html , 2002, printed on March 6, 2006; 2 pages | |
| | D6. | AUTHOR UNKNOWN, Paul Karrer Biography, Nobel Prizes, Nobel Prize in Chemistry, nobelprize.org , printed on January 5, 2007, 2 pages | |
| | D7. | COMAX Q10 Trademark Registration Abstract and copy of Specimen, Registration No. 1764014, registered April 13, 1993, 26 pages | |
| | D8. | CONSTANTINESCU, et al., "A Randomized Study of the Bioavailability of Different Formulations of Coenzyme Q10 (Ubiquinol)," <i>The Journal of Clinical Pharmacology</i> , 2007; 47: 1580-1586. | |
| | D9. | KANG et al., "Physicochemical studies of lidocaine-menthol binary systems for enhanced membrane transport," <i>International Journal of Pharmaceutics</i> , 206 (2000) 35-42. | |
| | D10. | KAPLUN-FRISCHOFF, et al., "Testosterone Skin Permeation Enhancement by Menthol through Formation of Eutectic with Drug and Interaction with Skin Lipids," <i>Journal of Pharmaceutical Sciences</i> , Vol. 86, No. 12, December 1997, pp. 1394-1399 | |
| | D11. | KOMMURU, et al., "A simplified chromatographic method for quantitative determination of coenzyme Q10 in dog plasma," <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 16 (1998) 1037-1040. | |

| | | |
|--|---|------------------------------------|
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| (Use as many sheets as necessary) | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|------|--|--|
| | D12. | KOMMURU, et al., "Stability and Bioequivalence Studies of Two Marketed Formulations of Coenzyme Q10 in Beagle Dogs," <i>Chem. Pharm. Bull.</i> 47(7) 1024-1028 (1999) | |
| | D13. | KOMMURU, et al., "Racemate and Enantiomers of Ketoprofen: Phase Diagram, Thermodynamic Studies, Skin Permeability, and Use of Chiral Permeation Enhancers," <i>Journal of Pharmaceutical Sciences</i> Vol. 87, No. 7, July 1998, pp. 833-840. | |
| | D14. | Nazzal et al., "Preparation and in vitro characterization of a eutectic based semisolid self-nanoemulsified drug delivery system (SNEDDS) of ubiquinone: mechanism and progress of emulsion formation," <i>International Journal of Pharmaceutics</i> 235 (2002) 247-265. | |
| | D15. | Nazzal et al., "Response Surface Methodology for the Optimization of Ubiquinone Self-Nanoemulsified Drug Delivery System," <i>AAPS PharmSciTech</i> 2002; 3 (1) article 3, pp. 1-9, Published: February 8, 2002, found at URL: http://www.aapspharmscitech.org | |
| | D16. | POUTON, Colin W., "Lipid formulations for oral administration of drugs: non-emulsifying, self-emulsifying and 'self-microemulsifying' drug delivery systems," <i>European Journal of Pharmaceutical Sciences</i> 11 Suppl. 2 (2000) S93-S98. | |
| | D17. | Shojaei et al., "Transbuccal permeation of a nucleoside analog, dideoxycytidine: effects of menthol as a permeation enhancer," <i>International Journal of Pharmaceutics</i> 192 (1999) 139-146. | |
| | D18. | SHRESTHA et al., "Aqueous Phase Behavior of Diglycerol Fatty Acid Esters," <i>Journal of Dispersion Science and Technology</i> , 28: pp. 883-891, 2007. | |
| | D19. | Siekman et al., "Preparation and Physicochemical Characterization of Aqueous Dispersions of Coenzyme Q10 Nanoparticles," <i>Pharmaceutical Research</i> , Vol. 12, No. 2, 1995. | |
| | D20. | WEBER, et al., "Intestinal Absorption of Coenzyme Q10 Administered in a Meal or as Capsules to Healthy Subjects," <i>Nutrition Research</i> , Vol. 17, No. 6, pp. 941-945, 1997. | |

| PROSECUTION DOCUMENTS | | |
|-----------------------|-----------------------|---|
| EXAMINER INITIALS | Cite No. ¹ | Name of document, date, application number, number of pages |
| | | USSN 10/953,328 (33503/US/3) |
| | E1. | Decision on Appeal dated May 11, 2011, USSN 10/953,328, 9 pages |
| | E2. | Office Action dated May 18, 2011, USSN 10/953,328, 9 pages |
| | E3. | Amendment and Response to Office Action and Terminal Disclaimer dated August 18, 2011, USSN 10/953,328, 9 pages |
| | E4. | Terminal Disclaimer dated September 2, 2011, USSN 10/953,328, 2 pages |
| | | USSN 11/223,718 (33503/US/5) |
| | E5. | Final Office Action dated July 14, 2011, USSN 11/223,718, 5 pages |

| | | |
|---|--|---|
| PTO/SB/08A and B (08-03) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | APPLICATION NO.: 10/674,268 | FILING DATE: September 29, 2003 |
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| Examiner Signature | /Rosanne Kosson/ | Date Considered | 09/30/2011 |

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¹ Applicant's unique citation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RK/